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"Regulations are cause of unease in industry"

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Regulations are cause of unease in industry



"From a regulatory stand point, there has been a fair amount of unease in the the life sciences sector in India. The Foreign Direct Investments (FDI) debate which has been under discussion for the last many months will need to be addressed. There are a few issues that surround the current status of the FDI policy in India, for instance," says Mr Utkarsh Palnitkar, partner and national head - advisory, national head of life sciences practice, KPMG India. Â

When asked about his expectations from the next government, Mr Palnitkar said, "The criteria for approval of brownfield investments must be very clearly articulated.Â The removal of the non-compete clause poses a threat to companies wishing to operate in niche areas." Â

"The Biotechnology Regulatory Authority of India (BRAI) Bill has been under discussion for about two years now. The bill was designed to promote biotechnology in the country by setting up an autonomous and statutory body to regulate the research, transport, import, manufacture and use of organisms and products of modern bio-technology. As in the case of FDI, the next government will have to make some clear decisions in this context too, mentioned Mr Palnitkar on the key biotech bill pending in the parliament.Â

Talking about the clinical trials, Mr Palnitkar remarked, "The clinical trials industry in India has undergone a lot of stress, given the long drawn process and uncertainty surrounding regulations that has stalled a number of trials in India. A balance between the protecting the rights of recruited subjects while providing clear norms for the conduct of trials is the dire need of the hour."

"At the core of the issue lies the lack of regulations which are stable and do not undergo changes time and again. The requirement of dealing with multiple regulatory authorities both at the central and state level adds to the complexity of doing business," Palnitkar said.Â

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